



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,512	05/01/2001	Rachel Meyers	MP100-185P1R2M	5523

7590 04/01/2005  
INTELLECTUAL PROPERTY GROUP  
MILLENNIUM PHARMACEUTICALS INC  
40 LANDSDOWNE STREET  
CAMBRIDGE, MA 02139

EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/846,512

Applicant(s)

MEYERS ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 83-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 94 and 96-104 is/are allowed.
- 6) ☒ Claim(s) 83-93 and 95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 07/29/02.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibit A (Sequence Alignment)

*22*

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/11/2005 has been entered. Since all the previously rejected claims are cancelled, the rejection set forth in the prior Office action is moot.

Claim 83-104 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found.

### ***Claim Rejections - 35 USC § 112***

Claims 83-93, and 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new matter rejection is made because of the new limitation "a polypeptide which is at least 95 % identical" to SEQ ID NO:2 or "a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:1 or 3", wherein the claimed polypeptide has

Art Unit: 1642

protease activity in base claim 83. The specification as originally filed does not reasonably communicate that the claimed invention is a method using a polypeptide which is at least 95 % identical to SEQ ID NO:2 or a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to the nucleotide sequence of SEQ ID NO:1 or 3, wherein the claimed polypeptide has protease activity. This new matter rejection is also made for claim 95, drawn to "a membrane-bound form of an isolated polypeptide".

Applicant states that support for the new claims are found in the previously presented claims, and pages 49-92 of the specification. However, the Office could not find support in the specification originally filed. Applicant is kindly requested to point out the support for the rejected limitation in the specification as originally filed since the support is not apparent to the Office.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 83-87, 89-91, and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. 6,294,663 (the '663 patent, issue, filed 02 March 2000).

Claims 83-87, 89-91, and 93 have two part active steps, i.e. contacting SEQ ID NO: 2 protein with a compound (as listed in claims 87, and 89) and determine whether

Art Unit: 1642

the compound interacts with the protein, wherein the interaction is determined by the various art-known method listed in claim 93.

The '663 patent discloses a protein sequence (i.e. SEQ ID NO: 2) that is at least 95 % identical to instant SEQ ID NO: 2 (note Exhibit A, the attached sequence alignment). The instant claims read on the immunohistochemistry assay of the prior art at Fig. 7.

***Allowable Subject Matter***

Claims 94, and 96-104 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Judy Ladrangan for Art Unit 1642 whose telephone number is 571-272-0536.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

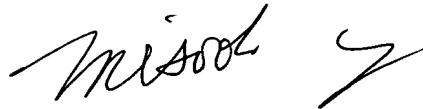
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1642

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642

A handwritten signature in black ink, appearing to read "Misook Yu", with a stylized flourish at the end.

GenCore version 5.1.6  
Copyright (c) 1993 - 2004 CompuGen Ltd.

## OM protein - protein search, using sw model

Run on: May 5, 2004, 15:45:40 / Search time 22 Seconds  
(without alignments)  
1063.026 Million cell updates/sec

Title: US-09-846-512-2

Perfect score: 2443  
Sequence: 1 MGENDPAPVAPSPRSLRG.....TRVSLFMDTHQERDLKT 453

Scoring table: BLOSUM62

Gapop 10.0, Gapext 0.5

Searched: 389414 seqs, 51625971 residues

Total number of hits satisfying chosen parameters: 389414

Minimum DB seq length: 0  
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%

Maximum Match 100%

Listing first 45 summaries

Database: Issued, Patents, AA:  
1: /cgn2\_6/ptodata/2/1aa/5a\_COMB.pep.\*  
2: /cgn2\_6/ptodata/2/1aa/5b\_COMB.pep.\*  
3: /cgn2\_6/ptodata/2/1aa/6a\_COMB.pep.\*  
4: /cgn2\_6/ptodata/2/1aa/6b\_COMB.pep.\*  
5: /cgn2\_6/ptodata/2/1aa/6c\_COMB.pep.\*  
6: /cgn2\_6/ptodata/2/1aa/6d\_COMB.pep.\*Pred. No. is the number of results predicted by chance to have a  
score greater than or equal to the score of the result being printed.  
and is derived by analysis of the total score distribution.

## SUMMARIES

Result No.	Score	Query Match	Length	DB ID	Description
1	2385.5	97.6	454	3	US-09-518-046-2
2	2206	95.3	455	3	US-09-261-416-2
3	1354	55.4	294	3	US-09-518-046-4
4	885	36.2	492	4	US-09-342-749-2
5	885	36.2	492	4	US-09-681-840-2
6	874	35.8	492	4	US-09-685-165A-895
7	862	35.3	157	3	US-09-518-046-23
8	696	28.3	283	3	US-08-807-151-1
9	696	28.3	283	3	US-08-807-151-1
10	674	27.6	417	4	US-09-478-957-1
11	669.5	27.4	798	1	US-08-200-900A-2
12	669.5	27.4	798	1	PCT-US94-00616-2
13	665.5	27.2	423	4	US-09-656-002-2
14	665	27.2	423	4	US-09-000-846-2
15	658	26.9	435	4	US-09-008-271A-6
16	658	26.9	435	4	US-09-851-588-8
17	656.5	26.9	376	4	US-09-820-002-2
18	656.5	26.9	406	4	US-09-851-588-6
19	585.5	26.0	256	2	US-09-027-137-3
20	585.5	26.0	256	2	US-09-644-600-3
21	585.5	26.0	256	2	US-09-644-600-3
22	580.5	25.8	255	3	US-08-944-483-67
23	579.5	25.7	638	2	US-08-681-151-3
24	571	23.4	418	1	US-08-508-448C-25
25	571	23.4	418	1	US-09-370-838-82
26	571	23.4	418	4	US-09-370-838-83
27	569	23.3	418	4	US-09-370-838-82

28	543.5	22.2	855	2	US-09-027-137-2	Sequence 2, Appl1
29	543.5	22.2	855	4	US-09-644-600-2	Sequence 2, Appl1
30	543.5	22.2	855	4	US-09-654-600A-2	Sequence 2, Appl1
31	539.5	22.1	232	1	US-08-508-448C-19	Sequence 13, Appl1
32	539	22.1	248	3	US-08-944-483-63	Sequence 63, Appl1
33	536.5	22.0	235	3	US-08-807-151-3	Sequence 3, Appl1
34	536.5	22.0	235	3	US-08-807-151-3	Sequence 3, Appl1
35	532.5	21.8	285	4	US-09-023-942A-26	Sequence 26, Appl1
36	526	21.5	338	4	US-08-991-761A-10	Sequence 10, Appl1
37	525.5	21.5	235	3	US-08-944-483-65	Sequence 65, Appl1
38	523.5	21.4	790	4	US-09-518-046-17	Sequence 13, Appl1
39	523	21.4	98	3	US-09-518-046-17	Sequence 17, Appl1
40	522.5	21.4	407	4	US-09-734-675-2	Sequence 4, Appl1
41	519	21.2	405	4	US-09-008-271A-3	Sequence 2, Appl1
42	507	20.6	314	3	US-09-907-784A-257	Sequence 257, App
43	507	20.6	314	4	US-09-905-125A-257	Sequence 257, App
44	507	20.8	314	4	US-09-902-775A-257	Sequence 257, App
45	507	20.8	314	4	US-09-902-775A-257	Sequence 257, App

## ALIGNMENTS

```
RESULT 1
Sequence 2, Application US/09518046
Patent No. 6294663
GENERAL INFORMATION:
APPLICANT: O'Brien, Timothy J.
TITLE OF INVENTION: Transmembrane Serine Protease Overexpressed
FILE REFERENCE: 061993CIP
CURRENT FILING DATE: 2000-03-02
EARLIER APPLICATION NUMBER: 09/261,416
NUMBER OF SEQ ID NOS: 153
SEQ ID NO. 2
LENGTH: 454
TYPE: PRT
ORGANISM: Homo sapiens
FEATURES:
OTHER INFORMATION: complete amino acid sequence of TADG-12
US-09-518-046-2
Query Match 97.6%; Score 2385.5; DB 3; Length 454;
Beet Local Similarity 97.8%; Pred. No. 1,3e-223;
Matches 444; Conservative 2; Mismatches 7; Indels 1; Gaps 1;
1 MGENDPAPVAPSPRSLRG...TRVSLFMDTHQERDLKT...PTIVIGIAL 59
1 MGENDPAPVAPSPRSLRG...TRVSLFMDTHQERDLKT...PTIVIGIAL 60
60 ILAALIGLTHPCGCKRCSFKCITLILACGVSDDCKGSENYCVRVGMNV 119
61 ILAALIGLTHPCGCKRCSFKCITLILACGVSDDCKGSENYCVRVGMNV 120
120 FTAAKMTKMSDDMKHYANVACAQIAPPSVSSDMLRVSSLEQPFEEVSI 179
121 FTAAKMTKMSDDMKHYANVACAQIAPPSVSSDMLRVSSLEQPFEEVSI 180
180 KVTALHSHVYVRGSGAGVVTLOCTACGHRGVSRTVGNMELSCQPMOASL 239
181 KVTALHSHVYVRGSGAGVVTLOCTACGHRGVSRTVGNMELSCQPMOASL 240
240 HLCGGSVITLRLITTAACVVDLYLPKSTIOVGLVLDNPARSHVETVYH 299
241 HLCGGSVITLRLITTAACVVDLYLPKSTIOVGLVLDNPARSHVETVYH 300
300 RLGNIDIALMGLAPITFENIOPVCLPNSSENFPGKVCMTSGCATBEGGAS 359
```

DB 301 RLGNDAIMKLAGLTFNEMIOVCLPENSEENFPDGKVCMTSGWATEDCGDASPVLTNHA 360  
 QY 360 AVPLISKNICNRHDVYGIITSPMLCAGYLTGCVNCCGDSGGLVCGEERLMLKVGATS 419  
 DB 361 AVPLISKNICNRHDVYGIITSPMLCAGYLTGCVNCCGDSGGLVCGEERLMLKVGATS 420  
 QY 420 FGICAEVNPDPVYTVTSPFLMIRHOMERDLKT 453  
 DB 421 FOICAEVNPDPVYTVTSPFLMIRHOMERDLKT 454

RESULT 2  
 US-09-261-416-2  
 / Sequence 2, Application US/09261416A  
 / Patent No. 6291663  
 / GENERAL INFORMATION:  
 / APPLICANT: O'Brien, Timothy J.  
 / TITLE OF INVENTION: TADG-12: A No. 6291663al Transmembrane Serine Protease  
 / TITLE OF INVENTION: Overexpressed in Ovarian Carcinoma  
 / FILE REFERENCE: D6192  
 / CURRENT APPLICATION NUMBER: US/09/261,416A  
 / EARLIER FILING DATE: 1999-03-03  
 / NUMBER OF SEQ ID NOS: 14  
 / SEQ ID NO 2  
 / LENGTH: 455  
 / TYPE: PRT  
 / ORGANISM: Homo sapiens  
 / FEATURE:  
 / OTHER INFORMATION: Amino acid sequence of TADG-12 encoded by nucleotides  
 / Patent No. 6291663  
 US-09-261-416-2

Query Match 90.3%; Score 2206; DB 3; Length 455;  
 Best Local Similarity 91.7%; Pred. No. 3,7e-206; Indels 10; Gaps 3;  
 Matches 421; Conservative 5; Mismatches 23;

QY 1 MGENDPFAVEAPFSPRSLFGLDLTKISVPADDAVAQAIIISLLPLKFP-PIIVIGIIL 59  
 DB 1 MGENDPFAVEAPFSPRSLFGLDLTKISVPADDAVAQAIIISLLPLKFP-PIIVIGIIL 60  
 QY 60 ILAALIGLHFDGSGKRCRCSFKCIELIARCDGVSDCKDEDEYRCVVGQNAVLQY 119  
 DB 61 ILAALIGLHFDGSGKRCRCSFKCIELIARCDGVSDCKDEDEYRCVVGQNAVLQY 120  
 QY 120 FTASMTMCSDDMKHAYANVACAQLGFPYSVSDNLVSLLEGOFREBFVSIIDHLLPDD 179  
 DB 121 FTASMTMCSDDMKHAYANVACAQLGFPYSVSDNLVSLLEGOFREBFVSIIDHLLPDD 180  
 QY 180 KVTALHSYVYREGCASGHVYTLCTACGHRGYSRIVGNNLSLQMPWQASLOFGY 239  
 DB 181 KVTALHSYVYREGCASGHVYTLCTACGHRGYSRIVGNNLSLQMPWQASLOFGY 240  
 QY 240 HLGGGVITPLMTITTAHCYVDLYLPKSWTIQVGLVSLDNPAPSHLVEKIVHSKXPK 299  
 DB 241 HLGGGVITPLMTITTAHCYVDLYLPKSWTIQVGLVSLDNPAPSHLVEKIVHSKXPK 300  
 QY 300 RLGNDAIMKLAGLTFNEMIOVCLPENSEENFPDGKVCMTSGWATEDCGDASPVLTNHA 359  
 DB 301 RLGNDAIMKLAGLTFNEMIOVCLPENSEENFPDGKVCMTSGWATEDCGDASPVLTNHA 360  
 QY 360 AVPLISKNICNRHDVYGIITSPMLCAGYLTGCVNCCGDSGGLVCGEERLMLKVGATS 419  
 DB 361 AVPLISKNICNRHDVYGIITSPMLCAGYLTGCVNCCGDSGGLVCGEERLMLKVGATS 420  
 QY 419 VCATSPGIGCAEVNKPDPVYTVTSPFLMIRHOMERDLKT 453  
 DB 417 VCATSPGIGCAEVNKPDPVYTVTSPFLMIRHOMERDLKT 455

RESULT 3  
 US-09-518-046-4

/ Sequence 4, Application US/09518046  
 / Patent No. 6294663  
 / GENERAL INFORMATION:  
 / APPLICANT: O'Brien, Timothy J.  
 / APPLICANT: Underwood, Lowell J.  
 / TITLE OF INVENTION: Transmembrane Serine Protease Overexpressed  
 / TITLE OF INVENTION: in Ovarian Carcinoma and Uses Thereof  
 / FILE REFERENCE: D6192CIP  
 / CURRENT APPLICATION NUMBER: US/09/518,046  
 / EARLIER FILING DATE: 2000-03-02  
 / EARLIER FILING DATE: 1999-03-03  
 / NUMBER OF SEQ ID NOS: 153  
 / SEQ ID NO 4  
 / LENGTH: 294  
 / TYPE: PRT  
 / ORGANISM: Homo sapiens  
 / FEATURE:  
 / OTHER INFORMATION: complete amino acid sequence of TADG-12  
 US-09-518-046-4

Query Match 55.4%; Score 1354; DB 3; Length 294;  
 Best Local Similarity 88.1%; Pred. No. 1.6e-123; Indels 8; Gaps 2;  
 Matches 258; Conservative 7; Mismatches 20;

QY 1 MGENDPFAVEAPFSPRSLFGLDLTKISVPADDAVAQAIIISLLPLKFP-PIIVIGIIL 59  
 DB 1 MGENDPFAVEAPFSPRSLFGLDLTKISVPADDAVAQAIIISLLPLKFP-PIIVIGIIL 60  
 QY 60 ILAALIGLHFDGSGKRCRCSFKCIELIARCDGVSDCKDEDEYRCVVGQNAVLQY 119  
 DB 61 ILAALIGLHFDGSGKRCRCSFKCIELIARCDGVSDCKDEDEYRCVVGQNAVLQY 120  
 QY 120 FTASMTMCSDDMKHAYANVACAQLGFPYSVSDNLVSLLEGOFREBFVSIIDHLLPDD 179  
 DB 121 FTASMTMCSDDMKHAYANVACAQLGFPYSVSDNLVSLLEGOFREBFVSIIDHLLPDD 180  
 QY 180 KVTALHSYVYREGCASGHVYTLCTACGHRGYSRIVGNNLSLQMPWQASLOFGY 239  
 DB 181 KVTALHSYVYREGCASGHVYTLCTACGHRGYSRIVGNNLSLQMPWQASLOFGY 240  
 QY 240 HLGGGVITPLMTITTAHCYVDLYLPKSWTIQVGLVSLDNPAPSH 285  
 DB 241 HLGGGVITPLMTITTAHCYVDLYLPKSWTIQVGLVSLDNPAPSH 293

RESULT 4  
 US-09-342-749-2  
 / Sequence 2, Application US/09342749  
 / Patent No. 6185196  
 / GENERAL INFORMATION:  
 / APPLICANT: Wong, Alexander K.C.  
 / APPLICANT: Tavetigian, Sean V.  
 / APPLICANT: Myriad Genetics, Inc.  
 / TITLE OF INVENTION: Tmp62 is a Tumor Suppressor  
 / FILE REFERENCE: 2318-202  
 / CURRENT APPLICATION NUMBER: US/09/342,749  
 / EARLIER FILING DATE: 1999-06-29  
 / EARLIER FILING DATE: 1998-06-29  
 / NUMBER OF SEQ ID NOS: 33  
 / SOFTWARE: PatentIn Ver. 2.0  
 / SEQ ID NO 2  
 / LENGTH: 492  
 / TYPE: PRT  
 / ORGANISM: Homo sapiens  
 US-09-342-749-2

Query Match 36.2%; Score 885; DB 3; Length 492;  
 Best Local Similarity 46.0%; Pred. No. 1.4e-77;  
 Matches 189; Conservative 53; Mismatches 149; Indels 20; Gaps 10;